IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of.:			
	Yoram Reiter		
Serial No.:	10/510,229		
Filed:	10/13/2004	Group Art Unit:	1648
For:	ANTIGEN-PRESENTING COMPLEX-BINDING COMPOSITIONS AND USES THEREOF		
		Attorney Docket:	**28429**
Examiner:	Lucas, Zachariah		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF CHARLES DELISI UNDER 37 CFR 1.132

I am presently employed as a faculty member at Boston University, where I am the Metcalf Professor of Science and Engineering and Dean *emeritus*. I received my Ph.D. degree from New York University, worked as a post-doctoral fellow in the laboratory of Donald Crothers at Yale University, where I developed new methods to compute the structure of biomolecules.

My research focuses on genomics and immunology. Since the beginning of my career, I have published more than 200 scientific articles in highly regarded journals and books, and have presented my achievements at many international scientific conferences.

I was elected Fellow of a number of societies including the AAS and the American College of Medical and Biological Engineers, and was awarded several research prizes including the Presidential Citizens' Medal (President Clinton) and the Smithsonian Platinum Technology Laureat for Pioneering Leadership. I am

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considered to be an expert in the fields of structural biology, immunochemistry, and computational genomics.

I have read the Office Action issued with respect to the above-identified patent application.

In this Office Action, the Examiner rejected claims 141-149, 151-155, 158 and 159 under 35 U.S.C. §103(a) as being unpatentable over Reiter (PNAS 94:4631-4636, 1997), further in view of the teachings Andersen et al., (WO 97/02342) who generated antibodies against mouse MHC-peptide complexes but contemplated more. Particularly, the Examiner states that the teachings of Andersen (1997) and Reiter (1997) could be used by any person skilled in the art to generate the antibodies against human MHC-peptide complexes as in the present application by Yoram Reiter.

Being an expert in the field of immunochemistry, I, Charles DeLisi, hereby state that the claimed invention, essentially a method of killing or damaging target human cells expressing or displaying a complex composed of a human antigen-presenting molecule and an antigen derived from a pathogen using antibodies capable of specifically binding such a complex, is novel and non-obvious over the cited references in that it satisfies a long-felt need which was recognized, persistent and not solved by others at the time of filing of the claimed invention.

I provide herewith documented evidence showing that for more than 15 years prior to the filing date of the invention discussed and claimed in the above-identified patent application, research groups have all failed in generating T-cell receptor (TCR)-like antibodies such as antibodies capable of binding human antigen-presenting molecules and an antigen derived from a pathogen, let alone using them for killing virus infected human cells. In evidence for this I provide herewith several experimental papers all showing failure to obtain TCR-like antibodies for killing virus infected human cells.

Thus, Tamminen WL., et al. (Eur. J. Immunol. 1987, 17:999-1006; see, in particular, Abstract; attached herewith) failed to obtain antibodies against MHC-viral peptide complexes.

In addition, Rubin B., et al., 1989 (Res. Immunol. 140:67-74; attached herewith) tested more than 1500 antisera but could not find any antibodies specific for complexes of MHC-insulin peptide (see Page 71, middle paragraph in Rubin et al.).

Chames P., et al., (PNAS, 2000, 97:7969-7974, attached herewith; see in particular Page 7970, left column, first paragraph), state that although highly desired for therapeutic applications, selection of antibodies that recognize MHC-peptide complexes is a difficult task. Chames et al. attempted to identify an antibody with specificity against a human MHC-peptide complex and identified one phage clone displaying Fab G8 which recognized HLA-A1-MAGE-A1 (a melanoma peptide) but not HLA-A1-MAGE-A3 complexes. However, when the soluble G8 Fab fragment, which was purified from the phage clone, was reacted with the target complex, the authors could not find conditions that eluted the antibody without also dissociating the β2m from the HLA-A1 heavy chain, thus, they failed to obtain a TCR-like antibody with specificity to human MHC-peptide complexes (see Page 7972, left column, second column in Chames et al.) which can be used in therapy. In addition, when the purified Fab G8 was immobilized to a surface through its hexahistidine tag, the bound antibody was devoid of affinity sufficient to kill target cells *in vivo*. Moreover, the purified Fab-G8 antibody failed to detect HLA-A1 cells incubated with the MAGE-A1 peptide (see Chames et al., Page 7972, left column, third paragraph), thus could not be used for detecting or killing cells presenting the MHC-peptide complex.

In this regard, Andersen et al., (WO 97/02342) have not provided any further teachings which could advance the use of TCR-like antibodies in human therapy in general and the treatment of virus infections, in particular.

The antibodies described in Andersen et al. (1997) and/or Reiter et al. (1997) are directed against mouse MHC-peptide complexes and not against human MHC-peptide complexes. As the mouse and human MHC molecules exhibit completely different chemical structures (with only 62.7 % of homology), such antibodies (e.g., Fab 13.4) cannot be used for targeting and treating human cells. It is my expert opinion that the antibodies contemplated by Andersen et al. are no more than an expression of a desired result rather than actual conception and reduction to practice.

Thus, it is my opinion that all the antibodies described in the prior art (including the publications of Andersen and Reiter) did not satisfy the long-felt need of generating TCR-like antibodies and killing virus infected human cells.

It is further my expert opinion that the claimed invention of the above-referenced patent application in fact satisfies the long felt need for antibodies which are specific to human complexes of antigen-presenting molecules and an antigen derived from a pathogen and therefore can be used for killing virus infected human cells.

Thus, the instant application demonstrates, for the first time, the ability to reproducibly generate antibodies with TCR-like specificity for human complexes composed of antigen presenting molecules and peptides derived from a pathogen. The ability of such antibodies to kill virus infected human cells renders them imperative tools for human therapeutic applications (e.g., for killing cells displaying the MHC-peptide complexes).

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United states Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

July 17, 2007

Charles DeLisi

Charles DeLisi

Enc.:

CV of Charles DeLisi

References:

- Tamminene WL., et al., Eur. J. Immunol. 1987, 17:999-1006;
- Rubin B., et al., 1989, Res. Immunol. 140:67-74;
- Chames P., et al., PNAS, 2000, 97:7969-7974;

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Date of Birth

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Education

1959-1963	City College of New York, B.A., Physics
1965-1969	New York University, Ph.D., Physics
1969-1972	Yale University, NIH Post Doctoral Fellow, Department of Chemistry

Employment

Current	Arthur G B Metcalf Professor of Science and Engineering; Professor of Physics; Professor of Pharmacology, Professor of Biomedical Engineering,
1999-present	Founder and Chair, All University Graduate Program in Bioinformatics
1990-2000	Dean, College of Engineering, Boston University
1987-1990	Professor and Chair, Department of Biomathematical Sciences, Mount Sinai School of Medicine; Professor Molecular Biology
1985-1987	Director, Health and Environmental Research, US DOE, Member, Senior Executive Service.
1981-1985	Section Chief, National Cancer Institute, NIH.
1977-1985	Senior Scientist, National Cancer Institute, NIH.
1972-1977	Staff Scientist, Theoretical Division University of California, Los Alamos National Laboratory
1971-1972	Senior Lecturer, Department of Engineering and Applied Science, Yale University

Graduate Students and Postdoctoral Fellows
Sponsored more than 60 graduate students and post-doctoral fellows.

Awards
Presidential Citizens Medal (President Clinton); Fellow American Institute of Medical and Biological Engineering; Fellow, American Association for the Advancement of Science; Smithsonian -Platinum Technologies 21st C. Pioneer Leadership Award (shared); Fellow, American Inst. Chemists; U.S. DOE Bicentennial Exceptional Service Award; C.C.N.Y Townsend Harris Medallist; Secretary of Energy Award of Distinction (Secretary Richardson);

Inventions and Disclosures
1. Jay A. Berzofsky, Cecelia S. Ouyang, Charles DeLisi, Hanah Margalit, J. L. Cornette, and K. Cease Patent No. 5,081,226 issued January 14, 1992 Synthetic peptides which induce cellular immunity to the AIDS virus and viral proteins.
2 Jay A. Berzofsky, Cecelia S. Ouyang, Charles DeLisi, Hanah Margalit, J. L. Cornette, and K. Cease Method to Predict Antigenic Sites Recognized by T Lymphocytes Such as for Design of Vaccines. Austr. Patent # 599208
3. Charles DeLisi, James L. Cornette, Ugur Sezerman, Rakefet Rosenfeld, Sandor Vajda: Patent No. 5,495,423 issued February 27, 1996. A general strategy for vaccine and drug design.
4. Charles DeLisi, James L. Cornette, Benjamin A. King, and Michael Silverman: Patent No 5,593,973 issued December 10, 1996. Molecular modeling method and system.
5. Charles DeLisi et al Methods for Designing Molecular Conjugates and Compositions Thereof US Application No. 09/052,530
6. DeLisi, et al Apparatus, Compositions and Methods for Proteome Profiling, Docket No. 701586-50852. International Applic No. PCT/US02/27261
7 Weng et al Improvement in Affinity of Proteins Recognizing Protein Antigens, Application No. 60/525,034
8 DeLisi YaoYu Wang, Chao Zhang and Zhiping Weng, Computational Methodology for Designing Optimal Chemotherapeutic Cocktails
9 DeLisi et al Synthesis of photolabile 2-(2-nitrophenyl)propyloxycarbonyl protected amino acids Docket No. 701586-054500-P USSN. Application No. 60/507,365

Invited Lectures

Typically 15-20 per year at universities, conferences, policy forums (Selected recent)
Keynote speaker, 14th International Conference on Genome Informatics, Yokohama Japan, 2003, Asia's Largest Genomics Conference
National Institute of Environmental Health Sciences, NIH Planning Meeting, Overview Address, 2003
Pardee Center Conference, BU: The Future of Human Nature, Organizer and Chair. Two day meeting of some of the Nation's leading researchers at the intersection of Psychology, Genetics and Computer science, 2003
Medical Technology Leadership Forum (Sen. David Durenberger, organizer), Harvard University;
From Double Helix to Human Sequence, NIH, Invited speaker. Two day Celebration of 50th Anniversary of Double Helix

Recomb2005 Stanislaw Ulam Memorial Award Lecture in Computational Biology
Second International Conference on Immunoinformatics, Co-Chair, 2005
Emerging Infectious Diseases, Organizer and Co-Chair, 1 Day meeting sponsored by Merck Pharmaceuticals, 2005
Keynote Speaker, Conf on Intelligent Systems for Molec. Biol. (largest international meeting in computational biology) 2006

Editorial Boards (selected)
Associate Editor and Co-Founder: Cell Biophysics, 1978-1984; Journal of Immunology, 1978-1983; Journal of Theoretical Biology, 1979-1985; International J. Computers in Biomedicine 1983- 1993; International J. of Genome Research, 1990 – 1993; American J. Physiology, 1985-1989; J. Genetic Analysis and Biomolecular Engineering 1995- 2001; Chaos, 2000-2004
J Synthetic and Systems Biology, 2005- ;Immunoinformatics, 2005-; Biology Direct, 2005-

Advisory Boards and Consultations (Selected)
Theory Advisory Committee, Los Alamos National Laboratory, 1987-1991; 1997-2001
Life Science Advisory Board, Oak Ridge Nation Laboratory, 1998- 2001
Science and Technology Steering Committee, Brookhaven National Lab, 1998- 2001
Scientific Advisory Board, Protein Databases Inc. 1988-1991
Scientific Advisory Board (Founding), Medimmune, Inc. 1987-1991
Advisory Committee on Information Technologies, U. S. Congress,
Office of Technology Assessment, 1988-1990
Board of Scientific Councilors, NCBI, NIH, 1998-; Chair, 2000-2002
Board of Advisors, Massachusetts Microelectronics Center, 1990-1991
Board of Governors, National Center for Genome Resources, 1993-1996
Board of Advisors, Human Genome Center, Lawrence Berkeley Lab, 1988-1991
Science Board, Santa Fe Institute, 1997-2000; 2001-pres
Member, NRC Committee to Assess Future Environments of National Institute of Standards and Technology, 2001
Member, NIH, NLM Ten Year Planning Committee, 2004-2005

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